Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive - Behavioral GroupTherapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students:Double Blind Randomized Clinical Trial.

Protocol summary

Study aim

Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive-Behavioral Group Therapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students.

Design

This clinical trial has two intervention groups and one control group, double blind and randomized ones.

Settings and conduct

After a diagnostic interview by a psychiatrist, patients who are diagnosed with social anxiety disorder are assigned randomly into intervention1, intervention2 and control groups. Evaluation is also performed three months after the intervention. The place of interview and intervention is the Department of Psychiatry and Clinical Psychology of Zanjan University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1. Tendency to participate in research; 2. A score of between 21 and 40 (mild to moderate social anxiety) in the SPIN; 3. 18 years and older; 4. Residence in Zanjan during research; 5. Being a student. Exclusion criteria: 1. At the same time receive psychological treatment; 2. Absence of more than two continuous sessions in therapeutic sessions; 3. Lack of participation in one of the three stages of evaluation; 4. History of psychosis, alcohol related disorders, bipolar disorder and personality disorders; 5.At the same time taking psychiatric medications.

Intervention groups

The first group will receive cognitive behavioral group therapy and the second group will receive metacognitive group therapy. The third group will not take any intervention on them.

Main outcome variables

Symptoms of social anxiety disorder; social phobia; social interaction; fear of negative evaluation; cognitive-attentional syndrome; negative meta-cognitive beliefs about risk and uncontrolledness; positive beliefs about worry; cognitive confidence; cognitive self-awareness; need for thought control

General information

Reason for update

Acronym

CBT & MCT

IRCT registration information

IRCT registration number: **IRCT20190518043626N1**
Registration date: **2019-05-23, 1398/03/02**
Registration timing: **prospective**

Last update: **2019-05-28, 1398/03/07**
Update count: **1**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

Fatemeh Rezaei Khodadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3353 3400

Email address

fatma.rezaei72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-01, 1398/03/11

Expected recruitment end date
2019-07-17, 1398/04/26
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive - Behavioral GroupTherapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students:Double Blind Randomized Clinical Trial.

Public title
Comparing The Efficacy Of Metacognitive Group Therapy And Cognitive - Behavioral GroupTherapy On Reducing Of The Symptoms And Metacognitive Factors Of Social Anxiety Disorder In Students.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tendency to participate in research. A score of between 21 and 40 (mild to moderate social anxiety) in SPIN. Age of 18 years and older. Residence in Zanjan city during research. Being a student.
Exclusion criteria:
At the same time receive psychological treatment. Absence of more than two continuous sessions in therapeutic sessions. Lack of participation in one of the three stages of evaluation. History of psychosis, alcohol related disorders, bipolar disorder and personality disorders. At the same time taking psychiatric medications. Score 15 to 25 in BDI-II.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
After diagnosis by a specialist, patients are assigned to treatment groups 1, 2, and control group, regardless of their specific characteristics, by software, so that all participants have the odds of being in groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
After selecting a sample, none of the sample individuals will know about the randomization process and allocation process to the groups. The data analyst is selected outside of the study, and all data will be encoded.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of zanjan University of Medical Sciences
Street address
Crossroads of Saadi, Gate of the Citadel, Shahid Beheshti Hospital
City
Zanjan
Province
Zanjan
Postal code
45156-13191
Approval date
2019-05-15, 1398/02/25
Ethics committee reference number
IR.ZUMS.REC.1398.036

Health conditions studied

1

Description of health condition studied
social anxiety disorder
ICD-10 code
F40.1
ICD-10 code description
Social phobias

Primary outcomes

1

Description
Symptoms of Social Anxiety Disorder.
Timepoint
Pre-test, post-test and follow-up (three months after the post-test).
Method of measurement
Conver social phobia Questionnaire(SPIN) and social interaction anxiety scale(SIAS).

2

Description
social phobia.
Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

Conver social phobia Questionnaire(SPIN).

3

Description

Social interaction.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

social interaction anxiety scale(SIAS).

4

Description

Fear of negative evaluation.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

Fear of negative evaluation of short form questionnaire(FNES-B).

5

Description

Cognitive-attentional syndrome.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

CAS-1.

6

Description

Negative metacognitive beliefs about risk and uncontrollability.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

MCQ-30.

7

Description

Positive metacognitive beliefs about worries.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

MCQ-30.

8

Description

Cognitive Confidence.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

MCQ-30.

9

Description

Cognitive self-awareness.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

MCQ-30.

10

Description

Need to control thought.

Timepoint

Pre-test, post-test and follow-up (three months after the post-test).

Method of measurement

MCQ-30.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Cognitive-behavioral group therapy Based on Hoffman model.

Category

Behavior

2

Description

Intervention group:Metacognitive group therapy.

Category

Behavior

3

Description

Control group:No intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan University of Medical Sciences.

Full name of responsible person

saeedeh zenoozian

Street address

Azadi Square, Zanjan University of Medical Sciences.

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
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Shoghli@zums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Saeedeh Zenoozian
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
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Person responsible for scientific inquiries

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Position
Student
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All information about the original outcome will be published with the likes of it.

When the data will become available and for how long

Get started since 1400.

To whom data/document is available

Researchers working in academia.

Under which criteria data/document could be used

Access to the documentation is possible for other researchers. Access to the documentation is possible with the researcher.

From where data/document is obtainable

Shaheed Beheshti Hospital, Zanjan, Department of Clinical Psychology, Dr. Saeedeh Zooszian. Tel: 09032180053 Zanjan Shahid Beheshti Hospital, Department of Clinical Psychology, Fatemeh Rezaei Khodadadi. Tel: 09130514827

What processes are involved for a request to access data/document

The required documentation will be shared only by mentioning the reason for the request by email or telephone.

Comments